FEB 2 5 2005

13 510(k) Summary

510(k) Number (if known): K050004

510(k) Summary for the Philips HeartStart FRx Defibrillator

1. **Date Summary Prepared**
   February 24, 2005

2. **Submitter's Name and Address**
   Philips Medical Systems
   Heartstream
   2301 5th Avenue, Suite 200
   Seattle, WA 98121

3. **Contact Person**
   Tish Treherne
   Regulatory Specialist
   Philips Medical Systems
   Heartstream
   Telephone: (206) 664-5283
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4. **Device Name and Classification Information**

Proprietary Name:	Philips HeartStart FRx Defibrillator
Common Name:	Defibrillator
Classification Names:	Automated External Defibrillator
Device Classification:	Class III
Regulation:	Automated External Defibrillator 21 CFR § 870.5310
Product Code :	MKJ

5. **Predicate Devices**
   The legally marketed device to which Philips Medical Systems, Heartstream claims equivalence for the Philips HeartStart FRx Defibrillator is the Philips HeartStart OnSite M5066A Defibrillator (K020715).

   The design and intended use of the FRx is substantially equivalent in safety and performance to the HeartStart OnSite M5066A.

6. **Device Description**
   The Philips HeartStart FRx Defibrillator is an automated external defibrillator indicated to treat victims of ventricular fibrillation, the most common cause of sudden cardiac arrest (SCA). Features of the Philips HeartStart FRx Defibrillator include self-testing and self-calibration, an impedance-compensating biphasic truncated exponential therapy waveform and a multi-parameter Patient Analysis System (PAS) for

determining if a shock is required and integrated human factors designs to facilitate use by lay responders and pre-connected electrodes.

A non-rechargeable lithium manganese dioxide battery powers the Philips HeartStart FRx Defibrillator with a minimum capacity of 200 shocks or 4 hours of operating time.

The HeartStart FRx Defibrillator issues voice instructions appropriate to the stage of the rescue and keeps pace with the user's actions. The defibrillator incorporates a shock-delivery protocol that pauses at predefined intervals to allow users to deliver CPR and otherwise continuously and automatically analyzes the patient's ECG to determine if a shock is needed. The defibrillator incorporates technologies that assess the ECG validity using both common mode and differential mode signals; these technologies were designed to ensure that a shock is not advised unless the defibrillator is applied to a patient in a shockable heart rhythm.

The HeartStart FRx Defibrillator utilizes the same biphasic, impedance-compensating exponential waveform used in previous-generation Philips AEDs. The HeartStart FRx Defibrillator delivers 150J shocks (nominal) after a shockable rhythm has been detected, and the user presses the shock button as instructed by the defibrillator (50J nominal with Infant/Child Key installed). The HeartStart FRx Defibrillator offers no manual-shock capability.

7. Intended Use

The HeartStart FRx Defibrillator is indicated for use on a person suspected to be in sudden cardiac arrest who is:

- Unresponsive when shaken
- Not breathing normally

8. Indications for Use

The HeartStart FRx Defibrillator should be used on a person you think is in sudden cardiac arrest. A person in sudden cardiac arrest is:

- Unresponsive when shaken
- Not breathing normally

If in doubt, apply the pads. A training class in CPR/AED use is recommended for anyone who may use the HeartStart FRx Defibrillator.

If the person is an infant or child younger than eight years old or weighs less than 55 lbs (25 kg), use the Infant/Child Key. If the child appears older/larger, do not use the Infant/Child Key. Do not delay treatment to determine the child's exact age or weight. If in doubt, do not use the Infant/Child Key.

9. Comparison of Technology Characteristics

The HeartStart FRx Defibrillator employs the same fundamental scientific technology as the commercially available Philips HeartStart OnSite M5066A Defibrillator.

10. Data Used in Determination of Substantial Equivalence

The HeartStart FRx Defibrillator employs the similar technologies to provide similar performance characteristics as the predicate device.

Testing demonstrates that the FRx performs in a manner substantially equivalent to the M5066A predicate and demonstrates that the introduction of the FRx does not raise and new issues of safety or efficacy.

11. Conclusion

The introduction of the HeartStart FRx Defibrillator does not present new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2005

Philips Medical System
c/o Ms. Tish Treherne
Regulatory Affairs Specialist
2301 Fifth Avenue, Suite 200
Seattle, WA 98121-1825

Re: K050004
Trade Name: Philips HeartStart FRx Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: III (three)
Product Code: MKJ
Dated: January 27, 2005
Received: January 28, 2005

Dear Ms. Treherne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

14 Indications for Use

510(k) Number (if known):

Device Name: Philips HeartStart FRx Defibrillator, model 861304

Indications for Use:

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Caution: Federal Law (USA) restricts this device to the sale by or on the order of a physician.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050004